

REMARKS

The Office Action has been carefully considered. Claims 30-66 are pending in the present application. Claims 30 and 35 has been amended. Claims 36-66 have been added and are pending in the present application. These claims find support in the originally-filed specification at, for example, page 2, lines 8-12, page 3, lines 5-11, page 6, lines 16-24, and original claims 1-29. The amendments are fully supported by the originally filed specification. No new matter has been introduced.

Reconsideration of the present application in view of the following remarks is respectfully requested.

I. FORMAL OBJECTION TO THE CLAIM

The Examiner has objected to the phrase “the second surface” in claim 35 because the Examiner alleges that “it is not clear if ‘the second surface’ [] is of the structure or of the tube-like portion.” (*See* Office Action, page 2). It is respectfully submitted that the “second surface” is that of the tube-like portion of the device. Claim 35 has been amended herein to recite “the second surface of the tube-like portion . . .” Since this amendment merely clarifies the claim language, no new matter has been introduced.

It is respectfully submitted that the claim objection has been overcome. Therefore, withdrawal of the claim objection and allowance of claim 35 are respectfully requested.

II. CLAIMS 30-32 AND 35 ARE PATENTABLE OVER SAUNDERS

Claims 30-32 and 35 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over United States Patent No. 5,780,807 to Saunders (“Saunders”). These rejections are respectfully traversed.

a) 35 U.S.C. § 102(b)

Independent claim 30 recites: “a first surface and a second surface . . . wherein at least a part of the first surface is covered with a coating comprising a first biologically active material to be released from the coating, wherein the second surface is substantially free of the first biologically active material and wherein the medical device is manufactured by a method . . . which comprises . . . (b) coating at least a portion of the first surface with a first coating material; and (c) ablating the coated structure with an ultrashort-pulse laser to

form at least one opening therein.” Claims 31 through 35 depend from claim 30 and, thus, also include the recitations of claim 30.

Saunders does not disclose or suggest that “at least a part of the first surface is covered with a coating comprising *a biologically active material*, and that the second surface is substantially free of the first biologically active material.” Saunders does not even disclose or suggest a biologically active material. Instead, Saunders is directed to a method for laser cutting metal stents which is then followed by electropolishing. After the explanation of the electropolishing technique, Saunders states that the “stents may be *further treated . . . by applying a biocompatible coating.*” Column 9, lines 26-27.

Thus, Saunders discloses a biocompatible coating as further treatment of the laser-cut metal stent. Saunders does not disclose or suggest that such biocompatible coating comprises a first biologically active material to be released from such coating. Moreover, even if Saunders’ biocompatible coating contained a biologically active material, there is no indication in Saunders that such biocompatible coating is only applied to part of the stent such that a second surface is substantially free of the first biologically active material, as required by the present claims.

“The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where . . . where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.” MPEP § 2113. As stated in the present specification, the “polymer coating, when applied by methods in the art, tends to create bridges at small gaps or corners between stent struts. Also, in the conventional methods, wherein a coating process takes place after a shaping process, it is almost impossible to selectively coat the stent. For example, it is impossible to coat one side of a stent without coating the other side or to apply different coatings to the outside and inside of a stent.” Present specification, page 1, line 32, to page 2, line 1. In contrast, “medical devices having multiple coating layers and a complicated geometry pattern can also be easily manufactured by the method of the present invention without flaws such as polymer-bridges at gaps or corners.” Specification, page 9, lines 21-23. Thus, even if Saunders disclosed applying a coating comprising a biologically active material, the resultant stent would not be the same as that presently claimed.

Saunders teaches a method of producing a stent by ablating a tubular wall to form a desired stent pattern using a laser beam. (*See* claim 1). However, Saunders does not teach

or suggest the use of ultra-short pulse lasers. Further, Saunders does not describe or suggest a method comprising coating a structure, such as a tubular wall, with a coating material for the release of a first biologically active material and ablating through both the tubular wall and the coating material to form openings in the coated structure. Nowhere in Saunders is there any teaching that both the coating material and the tubular wall are both ablated through.

Therefore, since Saunders does not teach each and every element of claims 30-32 and 35, it is respectfully requested that the rejection under 35 U.S.C. § 102(b) be withdrawn.

b) 35 U.S.C. § 103(a)

Alternatively, the Examiner has asserted that Saunders renders claims 30-32 and 35 obvious under 35 U.S.C. § 103(a) since it would have been obvious to one of ordinary skill in the art to coat the stent described in Saunders with a bioactive material. (*See* Office Action, page 2). Applicant respectfully disagrees with this position.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). "When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of the reference." *B.F. Goodrich Company v. Aircraft Braking Systems Corporation*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). The Federal Circuit has stated that it is improper to apply an "obvious-to-try" analysis under 35 U.S.C. § 103. *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725 (Fed. Cir. 1990). The relevant inquiry is whether the prior art suggests the claimed invention, and whether that prior art would have indicated a reasonable expectation of success to one of ordinary skill in the art. *In re O'Farrell*, 853 F.2d 894, 902-03 (Fed. Cir. 1988). Both the suggestion and expectation of success must be found in the prior art, not in Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Applicant submits that any rejection of the instant claims under § 103 based on Saunders would indicate the improper use of hindsight gained from applicant's own specification. Hindsight should be avoided in applying the nonobviousness requirement. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). Accordingly, the rejection is improper and applicant requests withdrawal of the rejection.

As stated above, Saunders does not disclose or suggest that at least a part of the first surface is covered with a coating comprising *a biologically active material*, and that the second surface is substantially free of the first biologically active material. Moreover, one of ordinary skill in the art would not find a suggestion or motivation to modify the teachings of Saunders to obtain the present invention. By stating that the stent may be further treated by applying a biocompatible coating, Saunders... One skilled in the art would not “treat” a stent by including a biologically active material in a coating. There is no indication in Saunders that the stent is used for drug delivery. Saunders does not even disclose or suggest the use of a stent for drug delivery purposes. Thus, one of ordinary skill in the art would not find motivation in Saunders to apply a coating comprising a biologically active material onto at least part of a first surface of the stent.

Saunders teaches that a biocompatible coating may be applied to a stent following electrochemical polishing, which step follows ablation of the tubular wall. (Col. 8, line 66-col. 9, line 27). By teaching that the coating should be applied after the tubular wall is ablated, Saunders teaches away from the present invention where the coating material is to be applied to the structure before ablation. There are particular advantages to coating the structure prior to ablation. For instance by first coating the structure and then ablating through both the coating material and the structure, openings in the coated structure can be formed that do not contain undesired coating material. If the structure were first ablated to form openings and then the coating material was applied to the ablated structure, undesired coating material could be present in the openings. In short, Saunders does not teach or suggest a process for making a medical device wherein a coating material and the structure covered by such material are ablated together by a laser as in the present invention.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 103(a) and allowance of claims 30-32 and 35 are respectfully requested.

III. CLAIMS 33-34 ARE PATENTABLE OVER SAUNDERS

Claims 33-34 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Saunders. This rejection is respectfully traversed.

As stated above, claims 33 and 34 depend from claim 30. Therefore, these claims include all of the limitations of claim 30. It was shown above that Saunders does not disclose or suggest the limitation that the coating material and the structure covered by such material are ablated together by an ultra-short pulse laser. Saunders actually teaches away

from simultaneously ablating a coating material and tubular structure by teaching that the coating should be applied following ablation of the tubular structure. (See Col. 8, line 66 - col. 9, line 27). Therefore, Saunders cannot render obvious a device comprising a first surface and a second surface wherein the coated structure is ablated with an ultra-short pulse laser to form at least one opening therein and at least a part of the second surface is covered with a second coating since Saunders teaches away from such limitations.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 103(a) and allowance of claims 33-34 are respectfully requested.

IV. CONCLUSION

As the claim rejections have been overcome, all pending claims are believed to be in condition for allowance. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

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Respectfully submitted,


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